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## **Cotrel-Dubousset (CD™) Spinal System 510(k) Summary**

- I. Company:** Sofamor Danek USA  
1800 Pyramid Place  
Memphis, TN 38132  
901-396-3133
- II. Proprietary Trade Name:** Cotrel-Dubousset (CD™) Spinal System
- Classification Name:** Pedicle Screw Fixation – Spondylolisthesis spinal fixation device system. Otherwise, spinal interlaminar fixation orthosis.
- III.** The CD™ Spinal System consists of rods, hooks, screws, connectors, cross connectors, and other components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components. The purpose of the CD™ Spinal System is to provide stabilization during the development of a solid spinal fusion. The CD™ Spinal System implant components are fabricated from ASTM F138 or its ISO equivalent stainless steel and may be sold sterile or non-sterile. Implant components made from different metal alloys must not be used together in a construct.
- IV.** The CD™ Spinal System is limited to non-cervical use in the posterior spine. The CD spinal screws, when used as pedicle screws with the CD™ Spinal System, are intended only for patients: (a) having severe spondylolisthesis (grade 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. Otherwise, the CD screws, when used in posterior fixation, are intended for sacral/iliac attachment only. Except for situations where stainless steel screws are attached to the pedicles of the lumbar and sacral spine via a posterior surgical approach in a CD construct for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the L5-S1 vertebral joint, the specific indications for the CD Spinal System (either stainless steel or titanium alloy versions) are the following:
1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by radiographic studies).
  2. Pseudoarthrosis

3. Stenosis
4. Spondylolisthesis
5. Spinal deformities: scoliosis, kyphosis, and lordosis
6. Fracture
7. Unsuccessful previous attempts at spinal fusion
8. Tumor resection

All of the CD hooks are intended for posterior thoracic and/or lumbar use only. CD cross connectors are intended for posterior thoracic, lumbar, and/or sacral use only.

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